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request that part or all of the records not be made available for public disclosure, the decision constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7. The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.49 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs (or delegatee).

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Deputy Assistant Secretary for Public Affairs (Media), Department of Health and Human Services. The agency will also make a reasonable effort to include in the letter an estimate of the volume of the records denied, unless providing such an estimate would harm an interest protected by an exemption under the Freedom of Information Act. This estimate will ordinarily be provided in terms of the approximate number of pages or some other reasonable measure. This estimate will not be provided if the volume of records denied is otherwise indicated through deletions on records disclosed in part.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 55 FR 1405, Jan. 16, 1990. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

21 CFR Ch. I (4–1–10 Edition)

§ 20.50 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search for and compile will be processed taking into account the staff-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionate adverse effects on agency operations.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.51 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the record or document shall be referred to the primary source of the record or document.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.52 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the

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National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22162, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.53 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will charge the person requesting the records for all of the fees involved pursuant to § 20.45.

[42 FR 15616, Mar. 22, 1977. Redesignated and amended at 68 FR 25286, 25287, May 12, 2003]

§ 20.54 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

[42 FR 15616, Mar. 22, 1977. Redesignated at 68 FR 25286, May 12, 2003]

§ 20.55 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. If the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, the Food and Drug Administration will take this failure into consideration in deciding whether that person has waived such exemption so as to require the Food and Drug Administration to promptly make the records available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994. Redesignated at 68 FR 25286, May 12, 2003]

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103